Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

BARD | MEDICAL

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the DigniShield Stool Management System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:
BARD Medical Division
C. R. BARD, Inc.
8195 Industrial Blvd.
Covington, GA 30014
Establishment Registration Number: 1018233

Contact:
Michele Davis, RAC
Regulatory Affairs Project Manager
Bard Medical Division
Tel: 770-784-6274
Fax: 770-385-4706

Date: May 8, 2014

Subject Device:

Trade Name:	Bard® DigniShield® Stool Management System
Common Name:	Rectal catheter
Classification Name:	Gastrointestinal tube and accessories
Regulation:	21 CFR 876.5980
Classification:	Class II
Product Code:	KNT

Legally marketed devices to which substantial equivalence is claimed:

- Bard® DigniShield® Stool Management System, K102391
- Bard® DigniCare Stool Management System, K073598
- ConvaTec Flexi-Seal® Signal™ Fecal Management System, K112342
- Hollister InstaFlo Bowel Catheter System Kit, K123804

Device Description

The Bard® DigniShield® Stool Management System is sold as a tray (kit) including a catheter, collection bag and stand alone components. The catheter consists of a retention cuff, trans-sphincteric zone, drainage tubing, inflation arm, irrigation arm, flush arm and piston valve connector. The retention cuff and trans-sphincteric zone are constructed from silicone and the drainage tubing is constructed from a Thermoplastic Elastomer (TPE) material. The system includes a collection bag which is manufactured from the same TPE material as the drainage tubing. The collection bag interfaces with the catheter and allows for the collection of fecal

matter. Additionally, the tray (kit) contains a tube clamp, syringe, lubricating jelly and odor eliminator. The tube clamp is used to retain medication during administration of medication. The syringe is used to facilitate the inflation of the cuff portion of the catheter. The lubricating jelly is provided to minimize patient discomfort and irritation of the rectum while the device is being inserted into the rectal vault. The biological odor eliminator may be used as an air freshener in the room.

Intended Use

The Bard® DigniShield® Stool Management System with odor barrier properties is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients and to provide access for the administration of medications. Adult use only.

Summary of Technological Characteristics

The table below summarizes the technological characteristics of the device as compared to the predicate devices.

Characteristic	Subject Device	Predicate Device (K102391)	Predicate Device (K073598)	Predicate Device (K112342)	Predicate Device (K123804)
Name	Bard DigniShield Stool Management System	Bard DigniShield Stool Management System	Bard DigniCare Stool Management System	Flexi-Seal Signal Fecal Management System	Hollister InstaFlo Bowel Catheter System Kit
Intended Use	Fecal management	Fecal management	Fecal management	Fecal management	Fecal management
Indications for Use	Bard DigniShield Stool Management System with odor barrier properties is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients and to provide access for the administration of medications. Adult use only.	Bard DigniShield Stool Management System is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients. Adult use only.	Bard DigniShield Stool Management System is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients. Adult use only.	For use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications	A bowel catheter system kit with odor barrier properties for diversion of liquid or semi-liquid stool to facilitate the collection of fecal matter in patients with little or no bowel control.

Characteristic	Subject Device	Predicate Device (K102391)	Predicate Device (K073598)	Predicate Device (K112342)	Predicate Device (K123804)
Name	Bard DigniShield Stool Management System	Bard DigniShield Stool Management System	Bard DigniCare Stool Management System	Flexi-Seal Signal Fecal Management System	Hollister InstaFlo Bowel Catheter System Kit
Device use, Sterility, Max Usage of Device	Sterile Use, Non Sterile, 29 days	Sterile Use, Non Sterile, 29 days	Sterile Use, Non Sterile, 29 days	Sterile Use, Non Sterile, 29 days	Sterile Use, Non Sterile, 29 days
Odor Barrier Properties	Yes	No	No	No	Yes
Medication Delivery	Yes	No	No	Yes	No
Catheter Material	Thermoplastic Elastomer and Silicone	Thermoplastic Elastomer	Silicone	Silicone	Thermoplastic
Accessories	Collection Bag Syringe Lubricating Jelly Odor Eliminator Tube Clamp	Collection Bag Syringe Lubricating Jelly Odor Eliminator	Collection Bag Syringe Lubricating Jelly Odor Eliminator	Collection Bag (3) Syringe Cinch Clamp	Collection Bag Syringe

Summary of Performance (Non-Clinical Testing) Data:
Non-clinical testing of the subject device for functional and structural characteristics has been performed. The subject device was substantially equivalent to the predicate devices for dimensional, functional and strength testing. Non-clinical performance testing supports that the subject device is substantially equivalent to the predicate device for administration of medication. Non-clinical odor barrier testing demonstrates the subject device decrease in odor permeation is substantially equivalent to the predicate device.

Biocompatibility testing of the subject device catheter met the requirements for a mucosal contacting device with prolonged exposure and the subject device tube clamp met the requirements for a skin contacting device with limited exposure per ISO 10993-1:2009, *Biological evaluation of medical devices and testing within a risk management process* and FDA Bluebook Memorandum G95-1, *Use of International Standard ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation of Testing* (May 1, 1995).

The subject device has been shown to be as safe and effective and substantially equivalent to the legally marketed, predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 9, 2014

C.R. Bard, Inc.
Michele Davis
Regulatory Affairs Project Manager
8195 Industrial Blvd.
Covington, GA 30014

Re: K133251
Trade/Device Name: DigniShield Stool Management System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: April 4, 2014
Received: April 7, 2014

Dear Michele Davis,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device evaluation
Center for Devices and radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number: K133251

Device Name: **DigniShield Stool Management System**

INDICATIONS FOR USE:
The Bard® DigniShield® Stool Management System with odor barrier properties is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients and to provide access for the administration of medications.

Adult use only.

Prescription Use ☒ *(Part 21 CFR 801 Subpart D)* and/or **Over-the-Counter Use** ☐ *(21 CFR 807 Subpart C)*

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S